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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,109	03/04/2002	Rosa Maria Perez Gomariz	G80-016 CIP	5154

21706 7590 07/22/2003

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ORANGEBURG, NY 10962-2100

EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/090,109	<b>Applicant(s)</b> PEREZ GOMARIZ ET AL.	
	<b>Examiner</b> Frank W Lu	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/446,352.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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**DETAILED ACTION**

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn to a pharmaceutical composition comprising VPAC1 receptor agonist with a pharmaceutically acceptable carrier, classified in class 530, subclass 300.
  - II. Claim 2, drawn to a pharmaceutical composition comprising VPAC2 receptor agonist with a pharmaceutically acceptable carrier, classified in class 530, subclass 300.
  - III. Claim 3, drawn to a pharmaceutical composition comprising PAC1 receptor agonist with a pharmaceutically acceptable carrier, classified in class 530, subclass 300.
  - IV. Claim 4, drawn to a method for treating and/or preventing septic shock, classified in class 435, subclass 7.1.
  - V. Claim 5, drawn to a method for treating and/or preventing septic shock, classified in class 435, subclass 7.1.
  - VI. Claim 6, drawn to drawn to a method for treating and/or preventing septic shock classified in class 435, subclass 7.1.
2. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are distinct and independent inventions in that they are directed to two different products. As a result, different and distinct searches will have to be performed. For

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example, the search required for Group I such as VPAC1 receptor agonist is not required for Group II.

Groups I and III are distinct and independent inventions in that they are directed to two different products. As a result, different and distinct searches will have to be performed. For example, the search required for Group I such as VPAC1 receptor agonist is not required for Group III.

Groups I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as a binding assay to test the binding between VPAC1 receptor agonist and VPAC1 receptor.

Group I and Groups V and VI are distinct and independent inventions in that they are directed to a product and two unrelated methods. As a result, different and distinct searches will have to be performed. For example, the search required for Group I such as VPAC1 receptor agonist is not required for Groups V and VI.

Groups II and III are distinct and independent inventions in that they are directed to two different products. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as VPAC2 receptor agonist is not required for Group III.

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Group II and Groups IV and VI are distinct and independent inventions in that they are directed to a product and two unrelated methods. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as VPAC2 receptor agonist is not required for Groups IV and VI.

Groups II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as a binding assay to test the binding between VPAC2 receptor agonist and VPAC2 receptor.

Group III and Groups IV and V are distinct and independent inventions in that they are directed to a product and two unrelated methods. As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as PAC1 receptor agonist is not required for Groups IV and V.

Groups III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different

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process of using that product such as a binding assay to test the binding between PAC1 receptor agonist and PAC1 receptor.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Since the restriction made by the examiner is based on an assumption which VPAC1 receptor agonist, VPAC2 receptor agonist, and PAC1 receptor agonist are different compounds, if applicant can provide evidence to show that all VPAC1 receptor agonists, all VPAC2 receptor agonists, and all PAC1 receptor agonists are the same, the examiner agrees to combine claims 1-3 together as Group I and claims 4-6 together as Group II.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

3. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

A handwritten signature in black ink, appearing to read 'Frank Lu', is positioned above the printed name.

Frank Lu  
July 15, 2003